

CLAIMS

1. A sternal closure system for reapproximating the left and right halves of a patient's longitudinally incised sternum during a surgical procedure in the thoracic cavity, this system comprising:

- a first, at least one anchor means, adapted to be disposed inside the left half of sternum;
- a second, at least one anchor means, adapted to be disposed inside the right half of sternum;
- at least one fixing means adapted for rigid connection to one another of said first, at least one anchor means, disposed within the left half of sternum, to said second, at least one anchor means disposed within the right half of sternum;
- an apparatus for simultaneous placing in the sternum said first, at least one anchor means, adapted for disposing within the left half of sternum, and said second, at least one anchor means, adapted to be disposed within the right half of sternum;
- a fixing apparatus for placing said fixing means adapted for rigidly connecting to one another said first, at least one anchor means, adapted to be disposed within the left half of sternum and said second, at least one anchor means, adapted to be disposed within the right half of sternum;

-an apparatus for removing said fixing means when it is necessary to perform a post-operative surgical procedure in the thoracic cavity,

whereby there is performed a rigid connection to one another of the left and the right halves of a patient's incised sternum during a surgical procedure within the thoracic cavity, as well as separation of the left and right halves of sternum closed in this way, in case of post-operative emergency surgical procedures.

2. A system according to claim 1 wherein said first, at least one anchor means, adapted to be disposed within the left half of sternum, and said second, at least one anchor means, adapted to be disposed within the right half of sternum, are screws having an external thread of one direction.

3. A system according to claim 1 wherein said first, at least one anchor means, adapted to be disposed within the left half of sternum, and said second, at least one anchor means, adapted to be disposed within the right half of sternum, are screws having an external thread of different directions.

4. A system according to claim 1 wherein said first, at least one anchor means, adapted to be disposed within the left half of sternum, and said second, at least one anchor means, adapted to be disposed within the right half of sternum, have heads provided with means for grasping and rotating them by said apparatus for simultaneous placing of said anchor means.

5. A system according to claim 4 wherein the heads of said first and said second anchor means are provided with means for their grasping by said apparatus for simultaneously placing said anchor means, said grasping means being generally shaped as grooves on the side surface of said heads.

6. A system according to claim 4 wherein the heads of said first and said second anchor means are provided with means for their rotation by said apparatus for simultaneously placing said anchor means, and these means for their rotation are generally cross-shaped slots on the end surface of said heads.

7. A system according to claim 4, wherein the heads of said first and said second anchor means are provided with means for their rotation by said apparatus for simultaneous placing of said anchor means, and these means for rotation are substantially shaped as hexahedral holes in the end face of said heads.

8. A system according to claim 1 wherein at least one fixing means adapted for rigidly connecting to one another said first, at least one anchor means, disposed within the left half of sternum to said second, at least one anchor means disposed within the right half of sternum is substantially shaped as a staple having a body and at least two legs extending from this body in a substantially perpendicular relationship, whereby said staple is adapted for rigidly connecting said first, at least one anchor means, to said second, at least one anchor means.

9. A system according to claim 8 wherein both said first, at least one anchor means, adapted to be disposed in the left half of sternum, and said second, at least one anchor means, adapted to be disposed in the right half of sternum, both have an inner axial passage adapted for disposing therein, substantially tightly, one of the corresponding legs of said staple.

10. A system according to claim 8, wherein said at least one fixing means is formed as a staple having a curved body and at least two slightly curved legs for tightly disposing in a respective inner axial passage of said first, at least one anchor means adapted to be disposed in the left half of sternum, and said second, at least one anchor means adapted to be disposed in the right half of sternum.

11. A system according to claim 1 wherein said first, at least one anchor means, adapted to be disposed within the left half of sternum, said second, at least one anchor means, adapted to be disposed within the right half of sternum, and said at least one fixing means, are all made of FDA approved metal or alloy, mainly of one of metal or alloy of the group, consisting of stainless steel, titanium, tantalum, alloys of titanium and tantalum.

12. A system according to claim 1 wherein said first, at least one anchor means, adapted to be disposed within the left half of sternum, said second, at least one anchor means, adapted to be disposed within the right half of sternum, and said at least one fixing means, are all made from FDA approved biodegradable material.

13. A system according to claim 1 wherein said apparatus for simultaneously placing in the sternum first, at least one anchor means, adapted to be disposed within the left half of sternum and said second, at least one anchor means adapted to be disposed within the right half of sternum, said apparatus comprising:

- a power means to generate a torque;
- a means for transmitting torque simultaneously to said first and said second anchor means;
- a means for searching and grasping simultaneously said first and said second anchor means;
- a means for retaining and simultaneously delivering said first and said second anchor means to said means for their searching and grasping.

14. A system according to claim 13 wherein said power means for generating a torque comprises one of the means of a group including an electric, pneumatic or hydraulic engine.

15. A system according to claim 13 wherein said means for transmitting torque simultaneously to said first and said second anchor means is generally a gear box having one drive shaft and at least two driven shafts.

16. A system according to claim 15 wherein, on the driven shafts of said gear box there are mounted spring-loaded heads forming said means for searching and grasping simultaneously said first and said second anchor means.

17. A system according to claim 13 wherein said apparatus for simultaneously placing in the sternum said first, at least one anchor means, adapted to be disposed within the left half of sternum, and said second, at least one anchor means, adapted to be disposed within the right half of sternum, comprises a frame means with vertical guides, and said means for retaining and simultaneously delivering said first and said second anchor means to said means for their searching and grasping comprises a spring-loaded cartridge means disposed within said frame means.

18. A system according to claim 17 wherein said means for retaining and simultaneously delivering said first and said second anchor means to said means for their searching and grasping comprises a spring-loaded cartridge means, disposed within said frame means and capable of stepping horizontal movement towards said means for searching and grasping said anchor means.

19. A system according to claim 13, wherein said apparatus for simultaneously placing in the sternum said first, at least one anchor means adapted to be disposed within the left half of sternum, and said second, at least one anchor means adapted to be disposed within the right half of sternum, contains a frame means with two horizontal plates disposed in parallel relationship and at least one vertical guide rigidly connected at least with one of these plates, and said means for retaining and simultaneous delivering of said first and said second anchor means to said means for their searching and grasping contains two spring-loaded rotary drums disposed between the plates within said frame means.

20. A system according to claim 19, wherein said means for retaining and simultaneous delivering of said first and said second anchor means to said means for their searching and grasping contains two spring-loaded rotary drums disposed between the plates within said frame means adapted to perform stepping synchronous swinging about their vertical axes towards said means for searching and grasping said anchor means.

21. A system according to claim 13 wherein, in said apparatus for simultaneously placing in the sternum said first, at least one anchor means, adapted to be disposed within the left half of sternum, and said second, at least one anchor means, adapted to be disposed within the right

half of sternum, said power means for generating torque, means for transmitting torque simultaneously to said first and said second anchor means, and means for searching and grasping simultaneously said first and said second anchor means, are formed as a single unit disposed on said at least one vertical guide of said frame means reciprocally relative to the latter.

22. A system according to claim 1 wherein said fixing apparatus for placing and removing said fixing means adapted for rigidly securing to one another said first, at least one anchor means, adapted to be disposed within the left half of sternum and said second, at least one anchor means, adapted to be disposed within the right half of sternum comprises:

- at least two levers, first and second, each of them having a proximal end and distal end, these levers being pivotally connected to one another and provided with handles at their distal ends and means for grasping heads of anchor means at their proximal ends;
- at least one third lever pivotally connected to said first lever or said second lever and provided with a handle at its distal end, and at its proximal end with a means for delivering the fixing means inside said first and said second anchor means, formed substantially as a pusher;

-a means for retaining and by the piece delivering of fixing means, formed substantially as a movable spring-loaded die with slots for disposing fixing means.

23. A system according to claim 22 wherein said fixing apparatus comprises at least two levers, a first and a second, each having a proximal end and a distal end, these levers being pivotally connected to each other, spring-loaded relative to each another and provided with handles at their distal ends, and means for grasping the heads of anchor means at their proximal ends.

24. A system according to claim 22 wherein said means for grasping the heads of anchor means are formed as two protrusions facing one another, one of them being disposed at the proximal end of first lever, and the second at the proximal end of second lever, and these protrusions have, at their free ends, recesses matching in shape the grooves on the side surface of heads of said anchor means.

25. A system according to claim 22 wherein said fixing apparatus comprises at least one third lever pivotally connected to said first lever or with said second lever and spring-loaded relative to this first or second lever, said third lever being provided with a handle at its distal end, and at

its proximal end with a means for delivering the fixing means inside said first and said second anchor means, which is shaped substantially as a pusher.

26. A system according to claim 22 wherein said fixing apparatus has a means for retaining and by the piece delivering of fixing means, comprising generally a movable spring-loaded die with slots for disposing these fixing means, this die being adapted to perform stepping linear movement in a guide, which is rigidly connected to said first lever or to said second lever of said fixing apparatus.

27. A system according to claim 1, wherein said fixing apparatus for placing said fixing means adapted for rigidly connecting together said first, at least one anchor means adapted to be disposed within the left half of sternum and said second, at least one anchor means adapted to be disposed within the right half of sternum, this fixing apparatus comprising:

- at least two levers, the first and the second, each of them having a proximal end and a distal end, these levers are pivotally connected to one another and provided with handles at their distal ends, as well as with means for grasping the heads of anchor means at their proximal ends;

- at least one third lever pivotally connected to a bearing plate rigidly secured on said first lever or said second lever, this third lever is provided with a handle at its free end, and pivotally connected by its middle to the means for delivering the fixing means inside said first and said second anchor means formed substantially as a pusher;
- a means for retaining and by the piece delivering of fixing means formed substantially as a cartridge enclosing spring-loaded fixing means located right up to one another.

28. A system according to claim 27, wherein said fixing apparatus contains at least two levers, the first and the second, each of them having a proximal end and a distal end, these levers are pivotally connected to one another and provided with handles at their distal ends, means for mutually fixing the handles when brought together, as well as by means for grasping the heads of anchor means at their proximal ends.

29. A system according to claim 28, wherein said means for grasping the heads of anchor means are configured as two protrusions facing one another, one of which is disposed at the proximal end of the first lever, and the second - at the proximal end of the second lever, and these

protrusions have at their free ends recesses matching in shape the grooves on the side surface of heads of said anchor means.

30. A system according to claim 27, wherein said fixing apparatus contains a single unit including at least one third lever, a means for retaining and by the piece delivery of fixing means formed substantially as a cartridge, and a means for delivering a fixing means inside said first and said second anchor means formed substantially as a pusher, this single unit is pivotally connected to the bearing plate rigidly mounted on said first lever or said second lever and is capable of folding back in the vertical plane to provide viewing of said means for grasping the anchor means or returning into operative position with simultaneous rigid fixing of the cartridge at the proximal ends of said first and second levers of the fixing apparatus.

31. A system according to claim 1, wherein the apparatus for removing said fixing means when it is necessary to perform a post-operative surgical procedure within the thoracic cavity contains:

- a hollow body provided with a handle extending therefrom, and in its lower part with a bifurcated stop;
- a spring-loaded grasping member movably disposed within this body;

-a pressure lever pivotally mounted on a pin within the upper part of hollow body, this pressure lever has a handle extending substantially in the same direction as said handle of hollow body and a free end located within the hollow body and operatively connected to said spring-loaded grasping member.

32. A sternal closure method for reapproximating a patient's left and right sternal halves during a surgical procedure in the thoracic cavity including the following successive steps:

- penetrating, before incising the sternum into left and right halves, at least one pair of anchor means in such a manner, that one of them is placed in the future left half of sternum, and the second in the future right half of sternum, one of anchor means in this pair being said first, at least one, anchor means adapted to be disposed within the left half of sternum, and the second of anchor means in this pair being the second, at least one anchor means, adapted to be disposed within the right half of sternum;
- repeating the procedure of placing said pairs of anchor means as many times as it is necessary to provide, on completion of a surgical procedure, a secure connection of the left and right halves of sternum;

- separating the sternum , by a surgical procedure, into left and right halves, and performing the surgical operation;
- reapproximating, on completion of the surgical operation within the thoracic cavity, the left and right halves of sternum, using conventional techniques;
- grasping said first and said second anchor means by their heads, bringing them towards one another, and thereby reapproximating, at a necessary distance, the left and right halves of the incised sternum;
- placing and fixing tightly the fixing means to secure the heads of said first and said second anchor means and creating thereby a rigid connection of the left and right halves of the incised sternum;
- repeating the procedure of placing the fixing means as many times as there are respective pairs of anchor means required to provide, on completion of a surgical operation, a secure connection of the left and right halves of sternum.